UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

December 17, 2002

MEMORANDUM

SUBJECT: EFED response to Bell Laboratories' errors-only comments on the Agency document "Comparative Risks of Nine Rodenticides to Birds and Nontarget Mammals"

TO: John Pates, Chemical Review Manager
Susan Lewis, Branch Chief

FROM: William Erickson, Biologist
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THRU: Stephanie Irene, Acting Chief
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The Environmental Fate and Effects Division (EFED) has reviewed Bell Laboratories' 30-day errors-only response to the Agency document "Comparative Risks of Nine Rodenticides to Birds and Nontarget Mammals" dated October 3, 2001. Bell Laboratories' comments of December 6, 2001 were prepared by C. W. Spragins. As stated in the Agency's October 23, 2001 cover letter for the assessment, the registrants' 30-day response should address only mathematical, computational, typographic, or other similar errors. Matters of policy, interpretation, or applicability of data will be addressed after the public comment period in accordance with the Agency's reregistration process for pesticides.

In response to error comments by Bell Laboratories, other rodenticide registrants, and the Rodenticide Registrants Task Force, EFED has made necessary computational and/or typographical corrections. However, EFED notes that many comments relate to policy, interpretation, or applicability of data, and those comments will be addressed along with public comments after the 60-day public-comment period.

Dear Mr. Pates:

Please accept the following comments as part of Bell Laboratories' response to EPA's document entitled "Comparative Risks of Nine Rodenticides to Birds and Nontarget Mammals" (CRA). Note that further commentary from Bell will be provided through the joint comments that will be submitted shortly by the Rodenticide Registrants Task Force.

1. **Comment:** The CRA includes a large amount of information on the toxicity and possible hazards associated with consumption by mammals or birds of rodenticides or rodents that have consumed rodenticides. The CRA is however, not a true risk assessment as risk takes into consideration hazard combined with exposure probability. Exposure models and probabilities are not considered in the CRA, hence it cannot be considered a risk assessment. The presumption of equal exposure in the document is in no way justified. As the Agency may be aware some other governments are looking at the ecological risks of various pesticides, including rodenticides. In
discussion of this topic with the UK authorities who are conducting a review at present, they pointed out that they would not jump to any conclusions or take actions until they "felt they had developed a reasonable model for assessing exposure", which they don't feel exists for rodenticides at present. A risk assessment cannot be completed without such a model.

> **EFED response:** It is well known that rodenticide baits are formulated to be lethal to rodents and a few other small mammals, and they are not selective to the target species. Although many factors influence which nontarget animals might be exposed to baits, many nontarget organisms are attracted to and consume grain-based baits. Predators and scavengers also feed on rats and mice or other target species, and they are not likely to avoid feeding on those that have eaten rodenticide bait. Thus, rodenticide baits also pose potential secondary risks. EFED believes that the potential for risks to birds and nontarget mammals is well established for some of these rodenticides.
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> The risk assessment is based on the available data. Registrants have not submitted the data that would be needed to assess the probability of exposure. These data have been outlined in a section on *Uncertainty and Data Needs* in the revised assessment. The methodology used is similar to that used in the Agency's "Comparative Analysis of Acute Risk From Granular Pesticides" (EPA 1992) and "A Comparative Analysis of Ecological Risks from Pesticides and Their Use: Background, Methodology, Case Study" (EPA 1998)[1]; both were reviewed by a FIFRA Scientific Review Panel. Concerning the latter analysis, the Panel noted the many scientific uncertainties in the method, yet agreed that it was a useful screening tool that provides a rough estimate of relative risk. The Panel made a number of helpful suggestions to improve the utility of the method, most of which are included here.

[1] See December 8-9, 1998 http://www.epa.gov/scipoly/sap/1998/index.htm

Risk conclusions are presented in tabular and graphical form based on two analyses of the available data. The first is a comparative ranking of the potential risk based on a comparative-analysis model, and the second is a tabular comparative rating of potential risk based on a qualitative "weight-of-evidence" assessment. Quantitative estimates of risk are used in both; however, the "weight-of evidence" assessment includes qualitative assessments of secondary risk based on mortality and other adverse effects reported in laboratory and field studies, operational control programs, and incident reports, as well as toxicokinetic data and residue levels reported in primary consumers. This approach is in concert with EPA's risk-assessment guidelines[2], where professional judgement or other qualitative evaluation techniques may be used to rank risks using categories such as low, medium, and high when exposure and effects data are limited or are not easily expressed in quantitative terms.

2. **Comment:** The tone of the CRA is disappointingly biased for what should be a scientifically objective review by a government agency. It appears the outcome was decided in advance and the authors constructed the document to prove the outcome. In blunt terms, the CRA reads like a Brodifacoum witch hunt. The CRA includes presentation of many lab dosing studies wherein the investigators record relatively black and white results which is quite appropriate provided they are presented for what they are (such data encompasses potential hazard, but only plays a part in assessing overall risk). Where the picture gets particularly muddled is in the presentation of incident data and in field studies wherein the investigators for example go out seeking animals to analyze after a product has been used in an actual treatment program for which it is registered. Such data has considerably more value in assessing actual risk but are also much more open to intepretation, speculation and bias. It is in the presentation of this type of data that the CRA falls woefully short of objectivity and the line between fact and speculation is repeatedly blurred. The authors give much space and weight to results from those investigators who concur with the outcome that appears to have been decided in advance. Some of these investigators are openly biased, for example Ward Stone has stated publicly that he "will see the end of Brodifacoum". Charles Eason developed Cholecalciferol for the lucrative New Zealand possum control market and has an interest in it's success. Brodifacoum (and Compound 1080) are direct and less expensive competitors. The Cholecalciferol product was registered for possums in New Zealand in about 1996, and since that time, Mr. Eason has generated an ongoing stream of studies and papers directed at the hazards of Brodifacoum use. While the authors of the CRA subject the considerable amount of information and analysis submitted by the RRTF to only brief review and harsh criticism, there appears to be little critical analysis of the cited data that concurs with the apparently predetermined outcome. While the Agency might argue that registrants also

[2] See Guidelines for Ecological Risk Assessment (EPA/630/R-95/002F, 1998) at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=12460

have an "agenda", registrants' data has always been subjected to far more critical review by the Agency than that of those who oppose pesticides or certain pesticides, and are thus forced to be far more scientifically certain of their results presented.

> **EFED response:** This is not an errors response. EFED believes that the risk assessment presents an accurate balance of results from available reports and the contention that it is biased is unsupported. EFED notes that the peer reviews and the credentials of the peer reviewers will be available in the public docket.

3. Much of the data presented in the second category as noted above (incident and actual field data) are from outside the United States where the use patterns are completely different. For example, Eason's New Zealand work refers to broadcast uses over large land areas. Field (non-commensal) uses do not exist in the U.S. for Brodifacoum, or other second generation compounds (except in the tiny exception of specific island restoration, which is irrelevant in the context of the CRA as such uses undergo extensive evaluation for ecologial impact on a specific case by case basis before they are approved. It is interesting that the authors, while mentioning the island use, fail to state that the purpose of such use is to actually preserve the native fauna and flora - i.e. a benefit of rodenticides. Brodifacoum is most often chosen for such uses due to its very high level of effectiveness). The CRA contains other examples of data from uses which do not exist in the U.S. as well, and fails overall to transparently make the distinction. Again, such data are useful in assessing hazard, but must be viewed very carefully in assessing actual risk.

> **EFED response:** This is not an errors response. EFED notes that the field studies are presented in a hazard context and confirm the potential for adverse effects in exposed nontarget animals, regardless of the use pattern or location. The Agency believes that the description of the field studies and their results provide useful information on the effects of rodenticides used outdoors.

4. The CRA makes repeated reference to an "2-gram bait pellet" or a 2-gram grain, eg. an oat groat and uses this to state that a "single pellet or grain" can deliver a lethal dose - an incorrect statement. These numbers are grossly inaccurate - all of Bell's commensal use pellets are 0.2 g or
less and the vast majority of field use pellets as well (a very large pellet, approaching 2 g, was used for the Anacapa island restoration project). Oats groats are about 0.1 g each. Conversely, the Agency chooses a 25 g non-target mammal for its calculations, which is at the extreme bottom end of the spectrum of mammals (only mice are that small as adults and they are typically the target species).

> **EFED response:** The size of the bait pellet has been corrected in the revised assessment.